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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/076,727   | 02/13/2002  | John T. Groves       | IB-1695             | 2093             |
| 8076   | 7590        | 06/30/2004           | EXAMINER            |                  |
| LAWRENCE BERKELEY NATIONAL LABORATORY<br>ONE CYCLOTRON ROAD, MAIL STOP 90B<br>UNIVERSITY OF CALIFORNIA<br>BERKELEY, CA 94720 |             |                      | SHIBUYA, MARK LANCE |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1639                |                  |

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/076,727

Applicant(s)

GROVES ET AL.

Examiner

Mark Shibuya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-24 are pending and subject to the instant Requirement for Restriction / Election.

#### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6, drawn to a micro-array device for determining adherence of selected cells, classified in class 435, subclass 288.3.
  - II. Claims 7-20, drawn to methods for cell adhesion of a particular cell type on a particular membrane or surface, classified in class 435, subclass 325.
  - III. Claims 21 and 22, drawn to a membrane bilayer surface forming a cell adhesion-free phospholipids bilayer surface, classified in class 435, subclass 287.9.
  - IV. Claims 23 and 24, drawn to a patterned surface formed by cell adhering and non-adhering phospholipid bilayer areas, classified in class 435, subclass 288.4.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group II and the Inventions of Groups I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another

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materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)).

In this case the micro-array device can be used to culture cell, which is another, materially-different process from determining adherence of selected cells.

Inventions of Group III and Inventions of Group IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the inventions of Group III have separate utility, such as preventing cells from clogging an interior capillary wall of a microfluidic device, which is separate from controlling the conditions or locations of the growth of cells. See MPEP § 806.05(d).

Inventions of Group I and the Inventions of Groups III, IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the micro-array device for characterizing the adherence of cells using different membranes with a spectrum of adherence capacity, does not depend upon the patentability of the Group III Invention of a membrane bilayer surface forming a cell adhesion-free phospholipids bilayer surface; or upon the patentability of the Group IV Invention of a patterned surface formed by cell adhering and non-adhering phospholipid bilayer areas. The

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subcombinations have separate utility, such as preventing cells from clogging an interior capillary wall of a microfluidic device through coating with adhesion-free unilamellar vesicles; or for controlling the conditions or locations of the growth of cells.

Inventions of Group II and the Inventions of Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case membrane bilayer surface forming a cell adhesion-free phospholipids bilayer surface can be used for prevention of cells clogging an interior capillary wall of a microfluidic device, which is a process that is materially different from that of characterizing cell adhesion of a particular cell type on a particular membrane or surface.

Inventions of Group II and the Inventions of Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in the process controlling the conditions or locations of the growth of cells, which is a process that is materially different from that of characterizing cell adhesion of a particular cell type on a particular membrane or surface.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and it is necessary to search for each one of the distinct subjects in places where no pertinent art to each of the other subject exists, restriction for examination purposes as indicated is proper. See, MPEP 808.02

3. This application contains claims directed to the following patentably distinct species of the claimed invention: Dopant molecules that are lipids, cell adhesion proteins of the immunoglobulin superfamily or selectins, receptor, or chemical moieties that chemically bind to a cell. See pp. 5-6 of the instant specification.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 14 and 23 are generic.

*Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a **listing of all claims readable thereon**, including any claims subsequently added.* An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

4. Claims 6, 13, and 19 are generic to a plurality of disclosed patentably distinct species comprising phosphatidylserine, dipalmitoylphosphatidic acid, distearoylphosphatidylglycerol, phosphatidylinositol, 1,2-dioleoyl-3-dimethylammonium-propane, 1,2-dioleoyl-3-trimethylammonium-propane, dimethyldioctadecylammonium bromide, 1,2-dioleoyl-sn-glycero-3-ethylphosphocholine, N-(7-nitrobenz-2-oxa-1,3-diazol-4-yl)-1,2-dihexadecanoyl-sn-glycero-3-phosphoethanolamine ammonium salt or N-1,2-dihexadcanoyl-sn-glycero-3-phosphoethanolmine triethylammonium salt.. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, even though this requirement is traversed.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.




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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Mark Shibuya  
Examiner  
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